

Remarks

Claims 36, 53, 57, 66, 68-70, 74-76, and 78-79 have been amended. New claims 82-111 have been added. Claims 1-35, 37, 44, 45, 51, 52, 54-56, 58, and 62-65 were cancelled in a previous Response(s). Claims 68-79 were previously withdrawn from consideration and are now presented again. Claims 36, 38-43, 46-50, 53, 57, 59-61, 66, and 67-111 are presented for the Examiner's review and consideration. Applicant believes the claim amendments and accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

Interview

The Applicant appreciates the courtesies extended by the Examiner during the telephone interview conducted on November 10, 2009. During this interview, the Examiner made suggestions to help clarify the present invention and agreed to reconsider the claims. The Examiner mentioned that the use of a cannula may put the claims in an allowable condition over the cited references. Also, in accordance with the Examiner's suggestion, it is noted that the bone growth promoting substance in claims 46 and 70 may include but is not limited to an osteoconductive substance and/or an osteoinductive substance.

Amendments

No new matter has been added by the amendment of claims 36, 53, and 68 and the addition of independent claim 84 made herein. These claims have been amended to clarify the steps related to a cannula. This concept is supported throughout the specification as originally filed. For example, *see* paragraphs [0067]-[0068]; Figures 18 and 19 of the published application.

No new matter has been added by the amendments to claims 57, 66, 69-70, 74-76, and 78-79 and the addition of new claims 82, 83, 85-96, and 109 made herein. As pointed out in previous Response(s), these claims are supported throughout the specification as originally filed.

No new matter has been added by the amendment of claims 97 and 98 made herein.

These claims have been added to clarify the steps related to expanding. This concept is supported throughout the specification as originally filed. For example, *see* paragraph [0060] and Figure 16 of the published application.

No new matter has been added by the amendment of claims 99 and 100 made herein. These claims have been added to clarify the steps related to cutting. This concept is supported throughout the specification as originally filed. For example, *see* paragraph [0057] and Figure 14 of the published application.

No new matter has been added by the amendment of claims 101-108 made herein. These claims have been added to clarify the steps related to a trocar. This concept is supported throughout the specification as originally filed. For example, *see* paragraph [0069] and Figure 19 of the published application.

No new matter has been added by the amendment of claims 110-111 made herein. These claims have been added to clarify the steps related to an instrument. This concept is supported throughout the specification as originally filed. For example, *see* paragraph [0069] and Figure 19 of the published application.

Restriction

Claims 68-79 have been withdrawn from consideration, as the Examiner asserts that these claims are directed to an invention that is independent or distinct from the originally-presented invention. In addition to the traversal presented in the October 22, 2009 Response, Applicant notes that during the interview, the Examiner suggested the addition of a generic claim would allow reconsideration of the withdrawal. In this Supplemental Response, Applicant is presenting claims as suggested. Specifically, claim 84 is generic as to tissue type and claim 68 is now dependent on claim 84.

Rejections under 35 U.S.C. §103(a)

Rudall in view of Kellogg

Claims 36, 38-40, 46-50, 53, 57, 59-61, 66, and 67 were rejected under 35 U.S.C. §103(a) as being unpatentable over Rudall et al. (Biology of the Skin and Hair Growth, American Elsevier Publishing Company, Inc., Chapter 5, Pages 75-88, 1965; hereinafter “Rudall”) in view of Kellogg (U.S. Patent No. 3,606,878; hereinafter “Kellogg”). For all reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

The invention, as currently claimed in independent claim 36, recites, *inter alia*, a method of using fetal body tissue, said method comprising inserting a removal apparatus into a donor percutaneously through a cannula, guiding the removal apparatus to a desired location within the donor’s body, separating portions of fetal tissue from other portions of the donor, moving the separated portions of fetal tissue along a passage in the removal apparatus by suction, maintaining viability of the removed separated portions of fetal tissue for harvesting and transplantation, and implanting the separated portions of fetal tissue in a patient.

As established in the previous Response(s), Rudall clearly describes a six inch open incision. Furthermore, the uterus was “exteriorized” from the body of the ewe to obtain access to the fetal lambs. *See* Methods A, Pages 76-77. In contrast, the method in claim 36 comprises, *inter alia*, 1) inserting a removal apparatus into a donor percutaneously through a cannula and 2) moving the separated portions of fetal tissue along a passage in the removal apparatus by suction. Nowhere does Rudall teach inserting percutaneously through a cannula or moving fetal tissue by suction.

Referring to Kellogg, the type of suction taught merely “help[s] retain the specimen in the cutter cup.” *See* Col. 1, Ln. 19. Furthermore, “[s]uction applied to the needle passage behind the cutter is communicated through the cutter to the needle passage forward of the cutter.” *See* Col. 2, Ln. 14. Moreover, the reference states “suction helps hold the specimen reliably within the cup or cavity of the cutter for subsequent removal after the needle is withdrawn from the patient.” *See* Col. 2, Ln. 19. In this reference, the suction is applied to the

hollow needle instrument forward of the cutter, not through a passage in the cutter itself. In contrast, the method of claim 36 comprises, *inter alia*, moving the separated portions of fetal tissue along a passage in the removal apparatus by suction. Nowhere does Kellogg teach moving fetal tissue along a passage in the removal apparatus.

Neither Rudall nor Kellogg, alone or in combination, teaches or suggests a method of using fetal tissue with the steps of 1) inserting a removal apparatus into a donor percutaneously through a cannula and 2) moving the separated portions of fetal tissue along a passage in the removal apparatus by suction. Thus, even if one of ordinary skill in the art attempted to combine these references, one would still be lacking elements and thus would not obtain the method as currently claimed. Therefore, the combination of Rudall and Kellogg is not sufficient to establish a proper case of *prima facie* obviousness, as the combination does not teach or suggest all of the limitations of the method as currently claimed.

Kantoff in view of Golbus

Claims 36, 40-42, 46-49, 50, and 67 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kantoff et al. (Blood 73(4):1066-1073 1989; hereinafter “Kantoff”) in view of Golbus et al. (The Western Journal of Medicine 150:423-430 1989; hereinafter “Golbus”). Claim 43 was rejected under 35 U.S.C. §103(a) as being unpatentable over Kantoff in view of Golbus and further in view of Martell (U.S. Patent No. 4,373,535; hereinafter “Martell”). For all reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

As established in the previous Response(s), Kantoff provides limited information on the method or apparatus used to obtain the cells from the donor and states only that the cells were obtained by exchange transfusion through the carotid artery of the donor. *See* Page 1066. Additionally, Kantoff’s teachings are limited to removal of blood from the fetus and replacement of the blood with maternal blood. In contrast, the method of claim 36 comprises, *inter alia*, 1) inserting a removal apparatus into a donor percutaneously through a cannula and 2) moving the separated portions of fetal tissue along a passage in the removal apparatus by suction. Nowhere does Kantoff discuss inserting a removal apparatus through a cannula or moving tissue with

suction.

As additionally established in the previous Response(s), Golbus's disclosure is limited to fetal biopsy and does not discuss maintaining viability of tissue or implanting tissue. In contrast, the method of claim 36 comprises, *inter alia*, 1) maintaining viability of the removed separated portions of fetal tissue for harvesting and transplantation and 2) implanting the separated portions of fetal tissue in a patient. Nowhere does Golbus discuss maintaining viability of fetal tissue or implanting fetal tissue.

Neither Kantoff nor Golbus, alone or in combination, teaches or suggests a method of using fetal tissue with the steps of 1) inserting a removal apparatus into a donor percutaneously through a cannula 2) moving the separated portions of fetal tissue along a passage in the removal apparatus by suction, 3) maintaining viability of the removed separated portions of fetal tissue for harvesting and transplantation, and 4) implanting the separated portions of fetal tissue in a patient. Thus, even if one of ordinary skill in the art attempted to combine these references, one would still be lacking elements and thus would not obtain the method as currently claimed. Therefore, the combination of Kantoff and Golbus is not sufficient to establish a proper case of *prima facie* obviousness, as the combination does not teach or suggest all of the limitations of the method as currently claimed.

Kantoff and Golbus in further view of Martell

Regarding the rejection of claim 43, the addition of a filter as described by Martell does nothing to remedy the deficiencies of Kantoff and Golbus as described above. Accordingly, Applicant respectfully submits that claim 43 is allowable over Kantoff and Golbus in view of Martell.

In light of the foregoing, Applicant respectfully requests reconsideration and withdrawal of these rejections under 35 U.S.C. §103(a).

Applicant: P. M. Bonutti
Application No.: 09/872,526
Examiner: A. Ramana

Conclusion

In light of the foregoing amendments and remarks this application is now in condition for allowance, and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned. The fees for extra dependent claims are believed to be due and are being paid via credit card. No other fees are believed to be due at this time. However, please charge any other fee required (or credit any overpayment) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 780-A02-014-7).

Respectfully submitted,
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